A community-based exercise and education scheme for stroke survivors: a randomized controlled trial and economic evaluation

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A community-based exercise and education scheme for stroke survivors: a randomized controlled trial and economic evaluation

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Objective: The evaluation of a community-based exercise and education scheme for stroke survivors.
Design: A single blind parallel group randomized controlled trial.
Setting: Leisure and community centres in the south-west of England.
Subjects: Stroke survivors (median (IQR) time post stroke 10.3 (5.4–17.1) months). 243 participants were randomized to standard care (124) or the intervention (119).
Intervention: Exercise and education schemes held twice weekly for eight weeks, facilitated by volunteers and qualified exercise instructors (supported by a physiotherapist), each with nine participants plus carers or family members.
Method: Participants were assessed by a blinded independent assessor at two weeks before the start of the scheme, nine weeks and six months. One-year follow-up was by postal assessment.
Main measures: Primary outcomes: Subjective Index of Physical and Social Outcome (SIPSO); Frenchay Activities Index; Rivermead Mobility Index. NHS, social care and personal costs. Secondary outcomes included WHOQoL-Bref.
Analysis: Intention-to-treat basis, using non-parametric analysis to investigate change from baseline. Economic costs were compared in a cost-consequences analysis.
Results: There were significant between-group changes in SIPSO physical at nine weeks (median (95% confidence interval (CI)), 1 (0, 2): $P = 0.022$) and at one year (0 (–1, 2): $P = 0.024$). (WHOQol-Bref psychological (6.2 (–0.1, 9.1): $P = 0.011$) at six months. Mean cost per patient was higher in the intervention group. The difference, excluding inpatient care, was £296 (95% CI: –£321 to £913).
Conclusion: The community scheme for stroke survivors was a low-cost intervention successful in improving physical integration, maintained at one year, when compared with standard care.

Introduction

Those who experience stroke aspire, where possible, to return to independent living and to achieve

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a good quality of life for themselves, their relatives and their carers.[1] Many stroke survivors want to return to the varied roles they had prior to their stroke and to integrate in their local communities.[2,3] The specific support and care needed after discharge from hospital to allow stroke survivors and their families to achieve these goals remains poorly understood.[4] This is especially pertinent as, unlike other disabling conditions, the onset of stroke is sudden, leaving the individual and the family ill-prepared to deal with the sequelae.[5]

Despite the emergence of multidisciplinary stroke pathways focusing on survivors and their families, the majority of these pathways end either at discharge or at best six months after stroke.[1] Community support for stroke survivors and their families remains fragmented and poorly coordinated between primary, community and voluntary sectors.[6] There are often clubs, societies, leaflets and other information and opportunities available to stroke survivors and their families, but people frequently need someone to help get them started.[7] Offering peer support can enable a greater understanding of the stroke, build confidence and develop feelings of personal empowerment.[8]

In the last few years the UK has seen the implementation of expert patient programmes that utilize lay trainers in a framework of peer support.

A recent review examined the effectiveness of the expert patient programme.[9] These programmes have been developed to offer education and support for people with long-term conditions, instilling confidence and control in the day-to-day management of their conditions. Four randomized controlled trials (RCTs), two specifically with arthritis sufferers and two with mixed conditions, showed only small changes in improvement in confidence and well-being.[10–13] The review highlighted issues around the design of the expert patient programmes compared with other seemingly more successful schemes in pulmonary and cardiac rehabilitation.[14,15] It was proposed that the pulmonary and cardiac rehabilitation schemes may be more successful as they targeted higher risk individuals but also that these programmes, unlike the expert patient programmes, included structured exercise and self-management advice. These programmes are run by health professionals and hence incur some cost to the health service.

Working in collaboration with local stakeholders and stroke survivors, we developed a community-based scheme designed specifically for people with a stroke. In keeping with the pulmonary and cardiac rehabilitation schemes it incorporated both an educational and exercise component. However, in line with the expert patient schemes it would be coordinated by peer volunteers.

The aim of the community scheme was to improve integration and well-being for stroke survivors and their families. This paper reports on the evaluation of this community scheme.

Methods

The effectiveness of the scheme was tested through a mixed-methods approach: a randomized controlled trial with both a clinical and an economic evaluation (both reported here), and a qualitative study, reported in a companion paper.[16]

Setting and participants

Participants were stroke survivors living in the community in Bath, North-East Somerset, North and West Wiltshire, Swindon, Bristol, and Weston-Super-Mare. They were aged at least 50 years at the time of stroke, had returned to living in the community for at least three months, and felt able to participate in group activities. Stroke survivors living in nursing homes were excluded. Recruitment was through local advertising using leaflets and posters, and through medical follow-up stroke clinics. The project coordinator (MR) met face to face with all the potential participants to explain the details of the community scheme, to ensure they met the criteria, and to gain consent. It was explained that at the end of the trial (after completion of the one-year postal questionnaires) all participants in the control group would be offered the opportunity to attend a community scheme, with an identical format to that offered to the intervention group.

Recruitment occurred between January and December 2004. Ethical approval for the trial

was obtained from Bath Research Ethics Committee (ref. no. BA533).

Randomization and concealment

Participants were randomly allocated to attend a community scheme (in addition to receiving standard care) or to receive standard care. Randomization occurred at the point of consent into the study. We used computer-generated numbers in geographical blocks of 18 participants, with the unit of randomization being the patient. The central aim of the schemes was to facilitate integration back into the local community, therefore randomization was stratified using 'geographical blocks' to allow participants to attend schemes run in their local area. Randomization was carried out centrally by an independent assistant who took no part in recruitment. Due to the nature of the intervention it was not possible to blind either the participants or the individuals involved in running the schemes, but outcome was assessed by a blinded assessor.

Control group

Participants in the control group received standard care and an information sheet detailing local groups and contact numbers. Standard care differed according to the area where the participants lived: in five of the six Primary Care Trust areas covered a stroke coordinator contacted or visited stroke survivors approximately six weeks after they returned home. In all areas stroke survivors were invited to a six-month review. At both of these points of contact stroke survivors were given information related to living with a stroke.

Intervention

Thirteen schemes, each with nine participants plus any partners, carers or family members, were held in leisure and community centres. Each scheme ran twice a week for eight weeks making a total of 16 sessions. Each session consisted of 1 hour of exercise followed by a short break, and 1 hour of interactive education. The exercise hour, run by a qualified local exercise instructor, supported by a physiotherapist (RH), was developed from previously published research.[17] The physiotherapist worked with all six of the different exercise instructors in giving initial training on the specific exercises to be used as part of the study, and then was available for support and regular updates. The exercises were designed specifically to improve balance, endurance, strength, flexibility, function and well-being. After an initial warm-up participants carried out a circuit that was adapted to their own capabilities and needs and could be easily progressed. Home exercise manuals were provided to support the programme and participants were encouraged to explore opportunities for on-going exercise at the end of the eight weeks.

The content of the interactive education component of each session was developed from previously established programmes,[18,19] from meetings with local health professionals, liaison with the local Stroke Association, and two in-depth semi-structured interviews with stroke survivors. Local outside speakers, for example, a stroke coordinator, the local Stroke Association manager, a benefits expert and a dietician, were invited to the group. These speakers were encouraged to carry out non-didactic, fun sessions wherever possible, focusing on group interaction. Interspersed with these sessions were goal-setting sessions, social sessions and some unstructured sessions that were set aside for the group to decide particular issues they wanted to discuss. A directory of local resources was developed for each area for participants to use after the end of the programme.

Volunteer workers were recruited to help coordinate the schemes and contributed in a variety of ways, including liaising with the participants, booking outside speakers, arranging transport and organizing refreshments. Some of the volunteers were also trained to help facilitate some of the sessions where no outside speaker was involved. A key role was to support the stroke survivors in the setting of goals. They also worked with the stroke survivors and their families in identifying ongoing exercise and other activities for when the scheme was over. The volunteers were trained and supported by a health psychologist, along with the scheme coordinator (MR).

Family members and carers were encouraged to attend the scheme and help in the exercise

hour. In addition, the health psychologist provided one dedicated session for family members in each scheme. This allowed an opportunity to raise any concerns and discuss problems in a supportive environment.

Assessments

All assessments were carried out by an assessor independent of the team and blinded to allocation. To minimize the introduction of bias all participants were contacted before each visit to remind them that the assessor was due to call and they should avoid disclosing their own group allocation.

All participants were initially assessed at home two weeks prior to the starting of the scheme (baseline). Face-to-face follow-up assessments were carried out again with all participants at nine weeks (one week after the end of the scheme for those in the intervention arm) and at six months. A postal questionnaire of primary outcome measures and WHOQoLbref was sent out at one year.

Outcome measures

Baseline measures of the Barthel Index[20] and Mini Mental State Examination[21] were carried out at the initial assessment.

Three primary outcome measures were selected to reflect the complexity of the intervention and the aims of the programme: the Subjective Index of Physical and Social Outcome (SIPSO), which was developed specifically to measure social and physical integration in stroke survivors[22–24]; the Frenchay Activities Index[25]; and the Rivermead Mobility Index.[26] Secondary outcome measures were: the Carer Strain Index[27]; Functional Reach[28]; Timed Up and Go Test[29]; WHOQoL-Bref (quality of life)[30]; and the Hospital Anxiety and Depression Scale.[31]

Sample size

A sample size of 100 in each group (80% power, 5% significance) will identify an effect size of 0.4 (a 2-point change in SIPSO) at six months follow-up. Previous work using SIPSO in participants six-month post stroke found a median score of 26–27 (range 0–40) and a natural improvement from 6 to 12 months in SIPSO of 1.3 point (equating to an effect size of 0.26).[24] We therefore considered an effect 1.5 times the natural improvement. To allow for drop-outs the planned recruitment was 144 participants per group. An effect size of 0.4 corresponds to a change in the FAI and RMI, of 4 points (SD = 10) and 1.6 point (SD = 4) respectively.

Analysis of data

Primary analysis was undertaken on an intention-to-treat basis, as specified in the study protocol. A per-protocol analysis, with stroke survivors who attended at least 12 of the 16 sessions, was also undertaken. Between-group differences were analysed and represented as absolute scores and change from baseline and represented as medians and interquartile range.

Differences between groups were tested using the Mann–Whitney *U*-test. A two-sided significance level of $P = 0.05$ was considered as significant. There was no attempt to adjust the *P*-value for the number of tests undertaken.

Economic evaluation

The economic evaluation was carried out from the perspective of the National Health Service (NHS), personal social services (PSS), and participants and their carers. We included all relevant direct costs incurred from the time patients entered the study until the second assessment, six months later. NHS costs included: primary care consultations, secondary care, community care and prescribed medication. Social care costs included: home care, meals on wheels, use of a day centre and social worker time. Personal costs included: private health care, social and domestic care, and transport.

Resource use data were collected prospectively during the trial. Patients were given a diary in which to note when they used any of the services identified, and when the assessor visited he asked follow-up questions to gain more information about the nature of any contact. We used unit costs in pounds sterling at 2005 prices.

We costed primary and social care using data from Curtis and Netten,[32] secondary care using the Department of Health tariff[33] and medication using the British National Formulary.[34] The cost of the intervention included hire of the venue, staff costs, transport, and sundry disposable items such as refreshments and small items of equipment. Personal costs were self-reported except travel where we used the AA schedule,[35] to cost car journeys reported as mileage. No adjustment for inflation was necessary.

We compared the cost from the different perspectives with the trial outcomes using a cost-consequences framework.[36]

Results

Two hundred and forty-four stroke survivors were registered of whom 243 were recruited to the project with 124 to usual care and 119 to the community scheme. The flowchart (Figure 1) shows the progression of participants through the assessments at nine weeks and six months and then the postal questionnaires at one year. Ten patients died during the trial (7 in the intervention and 3 in the control arm) and seven became too unwell to continue (5 intervention and 2 control). Further losses through withdrawal and loss of contact totalled 27 (13 intervention and 14 control). Overall, we had attrition losses of 70 (28%) in the study period. Eighty-four per cent of original participants were assessed at six months and the one year overall postal response was 71%. The drop-outs were not significantly different at either six months or one year between groups ($P = 0.280$, $P = 0.256$).

Table 1 shows the baseline characteristics for the two groups. In both groups there were slightly more male stroke survivors than female. The median baseline Barthel score was significantly lower ($P = 0.006$) in the intervention group. The Mini Mental State Examination score medians were the same at 28 out of a possible 30.

Sixty-one per cent of participants attended 12 or more of the 16 sessions. There were no differences in the results between the intention-to-treat and the per-protocol analysis, so only the intention-to-treat analysis is shown in this paper.

Primary outcomes

Tables 2 and 3 show the primary outcome results for both groups at baseline, nine weeks and six months for the home assessments (Table 2) and the one year postal primary outcome data (Table 3).

Between-group differences

At baseline, the total SIPSO score was significantly lower in the intervention arm. Analysis of the change in SIPSO from baseline found the only significant difference to be SIPSO physical at nine weeks ($P = 0.022$) and one year ($P = 0.024$). There were no other significant differences between groups.

The data were initially analysed using parametric ANCOVA. However, the parametric nature of the data meant that we changed our approach to non-parametric. Each variable has therefore been adjusted for its own baseline value.

Secondary outcomes

Tables 4 and 5 show the secondary outcome results for both groups at baseline, nine weeks and six months for the home assessments (Table 4) and the one-year postal survey (Table 5).

Between-group differences

There was evidence of a significant difference, with the intervention arm showing a greater improvement at six months for the psychological domain of WHOQol-bref.

There was no evidence of any differences between the intervention and control arms of the study at nine weeks, six months or one year for any of the other secondary outcomes.

Economic evaluation

Mean cost per patient was higher in the intervention group than in the control group, though variation within each group was high (Table 6). NHS costs were dominated by secondary care, which accounted for about two-thirds of the total. Eighteen participants from each group spent some time in hospital, and seven from the

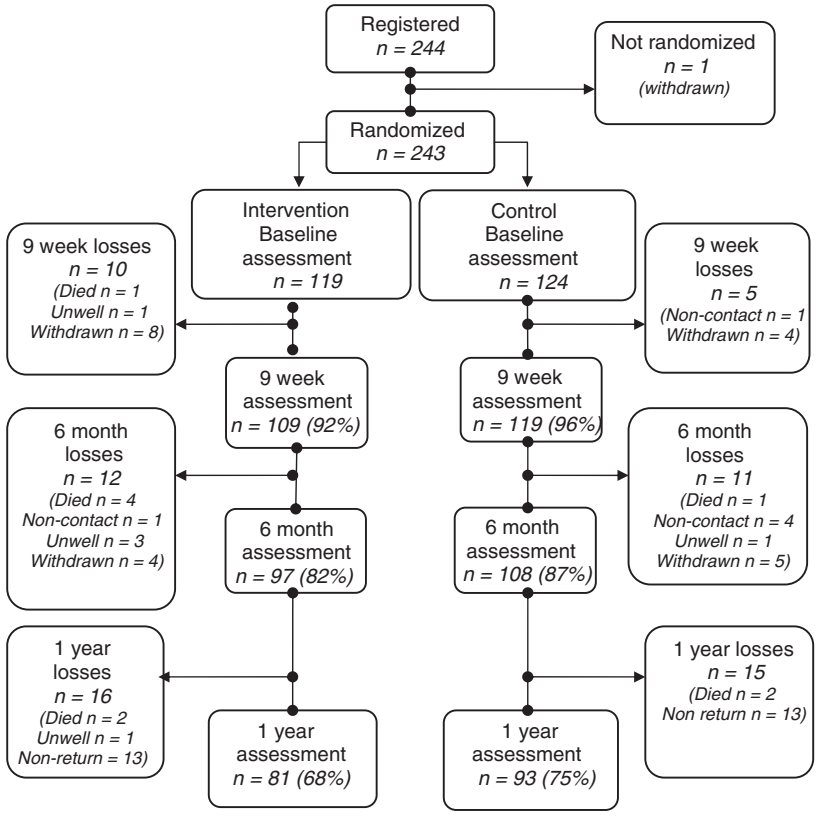

Figure 1 Participant flowchart.

intervention group and two from the control group had more than one stay. Primary care was largely GP costs; participants in the intervention group had a mean of 4.2 GP consultations and those in the control group had 3.3. Community care costs were higher in the intervention group because of more use of home care, meals on wheels and day centres. The intervention cost around £890 for 16 sessions. This included hire of the venue, payment to the exercise assistant, transport, refreshments, volunteer expenses and equipment. The cost per participant was therefore £99.

Participants in the intervention group cost on average £746 (95% confidence interval (CI) – £432 to £1924) more to care for than those in the control group. There is wide variation in the mean cost per participant, particularly those for secondary care as relatively few used these services.

Table 1 Baseline characteristics

Patient characteristics	Control ($n=124$)	Intervention ($n=119$)
Sex:		
Male	67 (54%)	65 (55%)
Female	57 (46%)	54 (45%)
Age, years:	$n=122$	$n=115$
Mean	70	71
SD	10.2	10.5
Side of stroke *n* (%):		
Left	57 (55%)	58 (59%)
Right	47 (45%)	41 (41%)
Barthel score*:	$n=124$	$n=119$
Median	19	18
IQR	17, 20	15, 20
MMSE score:	$n=124$	$n=118$
Median	28	28
IQR	25.2, 29	26, 29

*Mann–Whitney *U*-test, $P=0.006$.
MMSE, Mini Mental State Examination; IQR, interquartile range.

Table 2 Primary outcome data – home assessments at baseline, nine weeks and six months for the intention-to-treat population

Group	Control					Intervention				
	Baseline score	9 weeks		6 months		Baseline score	9 weeks		6 months	
		Score	Change score	Score	Change score		Score	Change score	Score	Change score
SIPSO										
Physical (/20):										
n	123	120	119	107	106	119	109	109	97	97
Median	13	14	1*	15	1***	10 ($P=0.004$)	12	1*** ($P=0.022$)	13	1
95% CI	12, 14	12, 15	0, 2	14, 16	0, 2	7, 11	10, 14	0, 1	11, 14	0, 2
Social (/20):										
n	124	119	119	108	108	119	109	109	97	97
Median	12	13	0	13	1**	12	13	0**	13	1
95% CI	11, 13	12, 14	–1, 2	11, 16	–1, 2	11, 13	12, 14	–2, 2	11, 14	–1, 3
Total (/40):										
n	123	119	118	107	106	119	109	109	97	97
Median	25	26	1**	27	2***	21 ($P=0.017$)	24	1***	26	2
95% CI	22, 26	23, 29	0, 2	23, 30	1, 3	19, 22	22, 26	0, 3	24, 29	0, 4
FAI (/45)										
n	121	117	114	106	104	116	106	103	96	93
Median	20	21	0	22	1*	15.5	17	1**	19.5	1**
95% CI	18, 22	20, 23	−1, 2	20, 25	0, 2	13, 19	15, 21	0, 2	17, 22	0, 3
RMI (/15)										
n	124	118	118	108	108	116	105	102	96	93
Median	12	12	0*	12	0	11	12	0*	12	0
95% CI	10, 14	10, 13	0, 1	10, 13	−1, 1	9, 12	11, 13	−1, 1	10, 14	−1, 1

Between-group comparisions: Mann–Whitney: significant *P*-values presented in table.
Within-group comparisons: Wilcoxon's test: *$P<0.05$, **$P<0.01$, ***$P<0.001$. Note: Change score = visit – baseline.

Excluding inpatient care, the cost difference between the two groups reduces to £296 (95% CI: −£321 to £913).

At the end of the study period all participants in the control arm were offered the opportunity to attend a group, 60 of the remaining 93 participants took up this offer.

Discussion

The community stroke scheme was shown to be more successful than standard care in improving physical integration, as demonstrated by the physical component of the SIPSO, and this improvement was maintained at a year. A significant improvement was also demonstrated on the psychological component of WHOQol-bref at six months. There was no evidence of any difference between the groups on any of the other primary or secondary outcome measures.

There were some potential limitations to this study. The study team and steering group, which included local stroke service users, aimed to ensure that we carried out a pragmatic study with a cohort as broad as possible; exclusion criteria were therefore kept to a minimum. In addition, the combined and complex nature of the intervention meant that some stroke survivors who attended were only able to fully participate in either the exercise component or the education. Our strategy may have ensured a representative sample but possibly at the cost of reducing the intervention's effectiveness and thus its outcome.

The choice of measures for this study was challenging due to the complex nature and breadth of the intervention. Other studies looking specifically

Table 3 Primary outcome data – postal survey at one year for the intention-to-treat population

Group	Control			Intervention		
	Baseline score	1 year		Baseline score	1 year	
		Score	Change score		Score	Change score
SIPSO						
Physical (/20):						
n	123	88	88	119	75	75
Median	13	12	–1*	10	11	0 ($P=0.024$)
95% CI	12, 15	10, 13	−2, 1	8, 12	9, 13	–1, 2
Social (/20):						
n	124	80	80	119	77	77
Median	12	13	0	12	12	0
95% CI	11, 14	11, 15	–2, 1	10, 14	10, 15	–2, 1
Total (/40):						
n	123	78	78	119	73	73
Median	25	25	–1	21	22	1
95% CI	22, 28	22, 29	–3, 2	18, 26	18, 27	−3, 5
FAI (/45):						
N	121	66	65	116	68	68
Median	20	21	1	15.5	21	0
95% CI	18, 23	17, 27	–5, 5	11, 22	15, 28	–6, 8
RMI (/15):						
N	124	82	82	116	64	62
Median	12	12	0*	11	11	0*
95% CI	9, 14	8, 13	−2, 1	8, 13	7, 14	–3, 1

Between-group comparisions: Mann–Whitney: significant *P*-values presented in table.
Within-group comparisons: Wilcoxon's test: $*P<0.05$. Note: Change score = visit–baseline.

at education provision after stroke have been able to demonstrate more changes: two previous studies have shown a reduction in anxiety,[37] and depression,[38] when using the Hospital Anxiety and Depression Scale, which this study did not show. These studies also showed changes in knowledge of stroke or self-efficacy which we did not measure in the randomized controlled trial but are explored in the parallel qualitative study.[16]

A recent review has shown positive changes following exercise programmes for older people, although these changes are often relatively short-lived.[39] A key component of the community scheme was the signposting on to other groups and clubs and a lot of emphasis was placed on ongoing exercise. This may account for the maintained improvement in physical integration at one year.

No changes in Timed Up and Go Test and Functional Reach measures were seen despite participants reporting constant improvements on their circuit record cards. These measures would not pick up higher level physical changes as in the SIPSO. The tests were also carried out in participants' houses and although utmost care was taken to ensure standardization the environment may have influenced the reproducibility of the measurement.

The use of a single individual as outcome assessor was a strength of the study. The assessor, by visiting stroke survivors in their own homes on three separate occasions, kept drop-out rates particularly low (85% of participants were assessed at six months) especially when considering the age and comorbidity of this group. As the only assessor the reliability of assessment was also high.

This scheme was developed as a transitional scheme for stroke survivors with attendance around six months after stroke, but for the purposes of the research, and in discussion with the steering group, it was broadened to any stroke survivors living at home. Surprisingly, a large number of people who had been at home well over a year approached the research team via community advertising and were keen to participate: there had been no other similar opportunities in

Table 4 Secondary outcome data – home assessments at baseline, nine weeks and six months for the intention-to-treat population

Group	Control					Intervention				
	Baseline score	9 weeks		6 months		Baseline score	9 weeks		6 months	
WhoQol-bref		Score	Change score	Score	Change score		Score	Change score	Score	Change score
Physical (/100):										
n	119	119	114	108	103	116	108	106	99	97
Median	53.6	53.6	0	57.1	3.0	53.6	57.1	3.6	57.1	3.6**
95% CI	49.4, 56.3	48.2, 56.2	–3.1, 3.5	53.8, 62.8	–1.6, 6.1	47.6, 57.9	46.4, 67.6	–2.9, 6.7	50, 57.8	–2.6, 6.5
Psychological (/100):										
n	116	119	112	108	101	115	109	106	99	96
Median	58.3	62.5	0	61.2	0	58.3	62.5	4.2*	62.5	6.2*** ($P=0.011$)
95% CI	56.2, 62.8	59, 67.8	–3.3, 2.3	58.3, 64.1	–2.3, 4.3	55.8, 62.7	58.8, 66.4	–2.6, 6.5	54.2, 68.3	–0.1, 9.1
Social (/100):										
n	115	118	111	107	100	114	106	103	99	95
Median	66.7	66.7	0	58.3	0	58.3	66.7	0	66.7	0
95% CI	60.1, 73.2	61, 73.3	–4.3, 3.3	52, 67.5	–5.3, 6.5	52.1, 65.5	59.2, 69.4	–3.4, 3.4	50, 75	–3.3, 6.7
Environmental (/100):										
n	119	120	115	108	104	114	109	105	99	95
Median	65.6	65.6	0	67.2	0	65.6	68.7	3.1	65.6	3.1*
95% CI	62.2, 70.5	59.7, 68.7	–6.2, 6.5	63.2, 71.1	–3.4, 5.7	62.1, 68.8	56.2, 72.6	–3.2, 6.4	59.4, 69.9	–0.1, 4.1
HADS										
Anxiety (/21):										
n	124	120	120	108	108	119	109	109	96	96
Median	5	4	–1*	3	–1***	4	4	0	3	–1**
IQR	4, 6	3, 5	–2, 1	1, 4	–1, 1	3, 5	3, 6	–1, 1	2, 5	–1, 1
Depression (/21):										
N	123	120	119	108	107	119	108	108	97	97
Median	5	5	0	4	–1*	6	6	0	5	0**
IQR	4, 6	3, 7	–1, 1	3, 6	–2, 1	5, 8	4, 7	–2, 2	3, 6	–2, 1
Total (/42):										
n	123	120	119	108	107	119	108	108	96	96
Median	10	10	–1	8	–2***	11	10	0	8	–1***
IQR	9, 11	9, 12	–2, 1	6, 9	–3, 0	10, 13	9, 12	–1, 2	6, 10	–2, 1
CSI (/13)										
n	88	80	76	68	60	84	77	69	60	54
Median	6	5	0 *	3	–1**	6	6	0	4.5	–1.5**
IQR	4, 8	4, 7	–1, 1	1, 5	–3, 1	5, 8	4, 7	–1, 1	2, 6	–3, 1

(continued)

Table 4 Continued

Group	Control						Intervention					
	Baseline score	9 weeks		6 months			Baseline score	9 weeks		6 months		
WhoQol-bref		Score	Change score	Score	Change score			Score	Change score	Score	Change score	
Functional Reach, cm												
n	123	119	118	108	107		117	109	107	97		96
Median	24	25	0.5	26	0		22	24	0	26		0
IQR	22, 27	22, 27	–2, 3	22, 28	–1, 3		20, 25	19, 26	–1, 3	21, 29		–2, 5
Timed Get Ip and Go Test, s												
n	113	109	107	96	96		103	95	92	83		83
Median	17.7	16.4	–1**	15.7	–1.5*		19.2	17.4	–1.4**	18.8		–2.3**
IQR	16.7, 21.2	14, 24.2	–2.7, 0	12.5, 22.9	–2.5, 0.5		16.7, 24.1	13.4, 23.2	–3.1, 1.3	15.5, 23.6		–3.3, 0.1

Between-group comparisons: Mann–Whitney: significant *P*-values presented in table.
Within group comparisons: Wilcoxon's test: $^{*}P<0.05$, $^{**}P<0.01$, $^{***}P<0.001$. Note: Change score = visit – baseline.
HADS, Hospital Anxiety and Depression Scale; IQR, interquartile range.

the time since their stroke. It was this keenness amongst the participants and the comprehensive individualised assessments carried out by the dedicated assessor that could have led to a marked Hawthorne effect; that is, the participants improved their performance simply because of the attention they received.

The scheme was intense: 2 hours twice a week for eight weeks. The reason for this was to ensure that the level of exercise was beneficial and in line with research on dose of exercise.[40] Many of the stroke survivors did find it difficult to attend all the groups. We carried out both an intention-to-treat and per-protocol analysis as we were keen to evaluate the actual effectiveness of the scheme. No significant difference between the two analyses was found, despite only 61% of the intervention group being able to attend at least 12 out of the 16 sessions.

The economic evaluation benefited from being part of a trial that involved close supervision and monitoring of the participants and this enhanced data quality. It is widely acknowledged that there is no 'gold standard' method of collecting resource use data from participants in trials; the choice of method is a matter of judgement and the 'best' way will depend on the setting, the type of participants, the amount and type of resources they are likely to use, and the trial budget. The resource use data in this trial were gathered using a combination of a diary (to record yes/no for each type of encounter) and a follow-up discussion with the assessor, who recorded more detailed information about each 'yes' response. For example, the participant might record that he or she had an outpatient appointment at the hospital and the assessor would then ask about the reason for the visit, any treatment or investigations carried out and the outcome. This method was particularly appropriate for this patient group, as contacts with health services featured prominently in their lives. We believe the data were of good quality.

Stroke survivors are heavy users of healthcare resources and although there is a substantial amount of literature around service use immediately after discharge from hospital,[41] we were unable to find any estimates of ongoing costs to compare with those estimated here. It is realistic to compare the cost of the intervention evaluated here with that of an expert patient scheme.[42] These

Table 5 Secondary outcome data – postal survey at one year for the intention-to-treat population

Group	Control			Intervention		
	Baseline score	One year		Baseline score	One year	
		Score	Change score		Score	Change score
WhoQol-bref						
Physical (/100):						
n	119	92	89	116	76	75
Median	53.6	53.6	0	53.6	53.6	– 3.6
95% CI	50.4, 57.6	50.8, 57.6	–3.7, 2.1	49.7, 56.7	48.4, 60.3	–9.9, 4.1
Psychological(/100):						
n	116	90	85	115	77	74
Median	58.3	62.5	4.2	58.3	60	0
95% CI	54, 62.8	58.1, 66.9	–2.8, 6.3	55.8, 65.3	57.4, 70.5	–5.3, 5.9
Social (/100):						
n	115	91	87	114	76	73
Median	66.7	66.7	0	58.3	62.5	0
95% CI	60.3,72.1	62.1, 71.5	–8.7, 8.7	52.1, 62.5	57.2, 67.5	–5.4, 11.7
Environmental (/100):						
n	119	91	88	114	78	74
Median	65.6	68.7	3.1*	65.6	65.6	0
95% CI	57.6, 70.1	62.2, 74.7	–1.1, 7.0	61.2, 69.8	58.2, 70.1	–4.4, 6

Between-group comparisions: Mann–Whitney: significant *P*-values presented in table.
Within-group comparisons: Wilcoxon's test: $*P<0.05$. Note: Change score = visit–baseline.

Table 6 Mean and incremental cost per patient

	Mean (SD) cost per participant (£)		Mean cost difference (95% CI) (£)
	Control	Intervention	
Primary care	167 (158)	204 (172)	
Outpatient care	333 (469)	223 (338)	
Inpatient care	927 (2231)	1377 (3725)	
Community care	281 (410)	347 (660)	
Medication	313 (314)	265 (188)	
All NHS	2021 (2412)	2415 (4019)	394 (–510 to 1298)
Social care	973 (2139)	1226 (1954)	
Intervention	0 (0)	99 (0)	
All NHS and PSS including cost of the intervention	2994 (3604)	3741 (4893)	746 (–432 to 1924)
Personal out-of-pocket costs	420 (969)	413 (843)	–7.62 (–260 to 245)

PSS, personal social services.

schemes use trained lay tutors and do not include exercise but comprise six weekly sessions of 2.5 hours each. This intervention has been costed at £250 per person and is higher than that of the community stroke scheme at £99 per participant.

One limitation of the economic evaluation is that we did not include costs and benefits associated with carer and volunteer time. A rigorous analysis would include, and report separately, estimates of the opportunity cost of this time and a valuation of the benefits gained (or lost). The inclusion of these is to some extent contentious.[43] We believe the exclusion does not detract form the main findings of this study. However, further research would add to our understanding of the societal effect of using informal care in similar settings.

At the end of the study period all participants in the control arm were offered the opportunity to

attend a group and for those who had signed up at the beginning of the study period this was two years later and often many years after their stroke. However, as mentioned previously 65% of these remaining participants took up this offer, reinforcing a genuine unmet need for stroke survivors living in the community.

Clinical messages

- Community-based exercise and education schemes for stroke survivors improved physical integration and psychological well-being.
- The schemes used trained and supported volunteers.
- The overall cost per patient of running the scheme was £99 (€120, $168).
- This was a well-received scheme that could be easily developed in partnerships with health, social care and voluntary sectors.

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Competing interests

No competing interests.

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